REMARKS

Applicant expresses appreciation to the Examiner for consideration of the subject patent application. This Response is in reply to the Office Action mailed January 6, 2009. Claims 1-44 were pending and were rejected under one or more statutory grounds.

Upon entry of this Response, claims 14, 15, 17-27 and 30-37 are pending. Claims 1-13, 16, 28, 29, and 38-44 have been canceled without prejudice. Claims 14, 17, 21, 26, 30, 32 and 33 have been amended.

Claim Rejections - 35 U.S.C. § 112

Claims 1-13 and 38-44 stand rejected under 35 U.S.C. § 112, for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-13 and 38-44 are currently canceled without prejudice.

Claim Rejections - 35 U.S.C. § 101

Claims 1-13 and 38-44 were rejected under 35 U.S.C. § 101 as being allegedly drawn to non-statutory subject matter.

Claims 1-13 have been canceled herein without prejudice.

Claims 14-37 were rejected under 35 U.S.C. § 101 as allegedly not being (1) tied to a machine or not (2) transforming underlying subject matter(such as an article or materials) to a different state or thing (e.g., in re Bilski et al, 545 F.3d 943, 88 USPQ 2d 1385 CAFC (2008), hereinafter referred to as "Bilski").

Independent claims 14 and 26 have been amended to include the limitations of "electronically generating a collection of individual summary reports each associated with a clinical trial report" by displaying on a substrate or an electronic display device various information related to the clinical trial report in a spatially distinct, predefined region. Thus, these methods transform the information contained in the initial trial reports and display it in a physically different manner on a physically different display (e.g., substrate or electronic display device). It is the information originally contained in the clinical trial reports that is being transformed. The present invention transforms a large degree of physical data (e.g., the information contained in various clinical trial reports) into a succinct, consistent and compact format.

This concept is very much analogous to the process at issue in *In re Abele*, 684 F.2d 902 (CCPA 1982), cited favorably in Bilski, in reference to which the Bilski court indicated that it had upheld a claim as reciting patentable subject matter where the claim specified that "said data is X-ray attenuation data produced in a two dimensional field by a computed tomography scanner." (Bilski, at 962). This data, said the court, clearly represented physical and tangible objects, namely the structure of bones, organs and other body tissues. Thus, the transformation of that raw data into a particular visual depiction of a physical object on a display was sufficient to render the claimed process patent-eligible.

This same principal applies in the present case. The present claims are limited to data associated with "clinical trials" – data that is directly related to physical attributes of human subjects (e.g., age, weight, physical symptoms, physical and/or psychological medical conditions, reactions to medications and/or treatments, etc.). The present system transforms this physical data from one form to another form. According to the analysis provided by the court in Bilski, this transformation is sufficient to qualify as patent-eligible subject matter. Thus, the presently claimed invention meets the second prong of Bilski, e.g., it transforms the underlying subject matter to a different state or thing.

Further, the independent claims have been amended to require "electronic" generation of the summary reports. These limitations comply with the first prong of Bilski.

Accordingly, Applicant respectfully requests that the rejections under 35 U.S.C. § 101 be withdrawn.

Claim Rejections - 35 U.S.C. § 102

Claims 1-2, 9-15, 22-27 and 34-38 (including independent claims 14 and 26) were rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by *Cognigen*.

In order to most succinctly explain why the claims presented herein are allowable, Applicant will direct the following remarks primarily to the independent claims 14 and 26, with the understanding that once an independent claim is allowable, all claims depending therefrom are allowable.

Independent claims 14 and 26 require the elements of "electronically generating a collection of individual summary reports each associated with a clinical trial report of the multiple clinical trial reports, each of the individual summary reports having a template common to other of the individual summary reports, and each of the individual summary reports being prepared by displaying on a substrate or an electronic display device [various information consistent from one of the summary reports to another of the summary reports]. (Emphasis added).

Thus, each of the summary reports produced share a common, consistent template, so that a reader of a plurality of the various summary reports always finds particular information displayed in a particular geographical area of the report, and in a particular geographical space. This aspect of the invention is not taught by the Cognigen reports – the various informational fields of Cognigen are all (with the possible exception of the Abstract), located in different areas on the report. Also, each of the informational fields of the Cognigen reports have different sizes (lengths), and so vary in the succinctness with which information is presented in these various zones.

The present invention advantageously always reports corresponding data in consistently the same area on a page and with the same degree of specificity (due to the size limitations imposed by the template). The spatially distinct, predefined data regions of the present invention are always consistently presented in the same place from one summary to another, and occupy the same footprint on each summary.

In addition, while it was held in the Office Action that the Rubino report includes a patient characteristic region (the "Methods" section is indicated), the Hammel reference cited does not include any such information (its "Methods" section does not

include patient characteristic information). Thus, the Cognigen reports cited do not consistently present the same information in the same location from one report to another, as is presently claimed.

With regard to the rejections of dependent claims 22 and 34, these claims require that the arm-specific region includes "information of a type selected from the group consisting of arm comparison information comparing each arm of the clinical trial; arm stratification information relating to stratification of patients treated in the clinical trial; and arm-specific information relating to at least one arm of the clinical trial." This limitation is neither taught not suggested by the Cognigen references.

CONCLUSION

In light of the above, Applicant respectfully submits that pending claims 14, 15, 17-27 and 30-37 are in condition for allowance. Therefore, Applicant requests that the rejections and objections be withdrawn, and that the claims be allowed and passed to issue. If any impediment to the allowance of these claims remains after entry of this Amendment, the Examiner is strongly encouraged to call the undersigned at (801) 566-6633 so that such matters may be resolved as expeditiously as possible.

Provision is made herewith for payment of the fee required for a one-month extension of time to file this response. It is believed that no additional fee is due herewith. However, the Commissioner is hereby authorized to charge any additional fee or to credit any overpayment in connection with this Amendment to Deposit Account No. 20-0100.

DATED this 6th day of May, 2009.

Respectfully submitted,

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